

REMARKS

In the Office Action of May 1, 2003, claims 1-7, 10, and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Niermann et al. (U.S. Patent No. 5,354,267) in view of Russo (U.S. Patent No. 5,775,325).

Additionally, in the Office Action, claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Niermann and Russo and further in view of Reynolds (U.S. Patent No. 5,370,610).

Also in the Office Action, claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Niermann, Russo Reynolds, and further in view of Loescher et al. (U.S. Patent No. 5,005,568).

Also, in the Office Action of May 1, 2003, claim 12 was rejected under 35 U.S.C. §103(a) as being unpatentable over Niermann, Russo, and further in view of Reynolds.

Applicants respectfully traverse the §103(a) rejection to claim 1 over Niermann in view of Russo. When one skilled in the art views prior art references in their entirety, he or she must have some motivation to combine one reference with the other to solve a problem for the resulting design to be obvious under §103(a). Here, when one skilled in the art views both Niermann and Russo, he or she is not motivated to produce a respiratory suction apparatus as claimed in claim 1.

Niermann seeks to provide a new and improved irrigation and suction apparatus that may be used during ventilation of a patient (see Niermann at column 1, lines 5-7).

Niermann discusses previous irrigation and suction apparatuses known in the art (see Niermann at column 1, lines 12-22):

These patents disclose irrigation and suction apparatus for use during patient ventilation wherein the irrigation fluid is introduced, or injected typically under some pressure, into the apparatus and is directed simultaneously to both the trachea and lungs of the patient and to the exterior, and/or internal lumen, of the suction catheter to wash the catheter and to remove or dislodge any materials such as secretions or mucous from the patient's lungs which may have become lodged in the internal lumen of the catheter or lodged in the suction holes at the catheter's tip.

Niermann further states that it is undesirable to have an irrigation and suction apparatus where irrigation fluid may be directed simultaneously to both the patient and the exterior of the catheter. In this regard, Niermann states that a better arrangement exists in having an irrigation and suction apparatus that is capable of directing irrigation fluid to the patient in a step completely isolated from directing irrigation fluid to both the patient and the exterior of the catheter (see Niermann at column 1, lines 23-30):

It is believed that it is more effective and therefore preferable for patient irrigation and catheter washing or flushing to introduce the irrigation fluid in one step of operation solely to the trachea and lungs of the patient and solely to the catheter in a second step of operation thereby assuring more positive flow of the irrigation fluid to the patient and catheter in separate steps of operation.

The entire disclosure of Niermann is therefore directed to providing an irrigation and suction apparatus that is capable of directing irrigation fluid solely to the patient, and then may be reconfigured so that irrigation fluid may be directed solely to the exterior of the catheter to clean the catheter (see Niermann at column 1, lines 38-43).

Niermann states that it is undesirable to introduce irrigation fluid when the catheter is

present because doing so would cause mucous on the exterior of the catheter to be flushed into the lungs of the patient (see Niermann at column 1, lines 42-45). Niermann therefore discloses an apparatus that provides irrigation fluid either solely to the catheter (see Figure 2 of Niermann) or solely to the patient (see Figure 3 of Niermann). In this regard Niermann **explicitly teaches** that it is disfavored to provide for an irrigation and suction apparatus that is configured for providing irrigation fluid to the patient while the irrigation is also capable of contacting the catheter. As stated, such a configuration is expressly described as being a problem that exists in the art from which the disclosure of Niermann seeks to alleviate.

Turning now to Russo, this reference discloses in Figures 5 and 6 a flushing port assembly 38 that is in communication with a passage 34 while the suction catheter 44 is present in the passage 34. When lavage solution is administered through the flushing port assembly 38, cleaning of the suction catheter 44 may take place (see Russo at column 5, lines 40-42). An entrance seal 22 contains the lavage solution to the passageway 34 and does not permit the lavage solution from entering the patient's airway (see Russo at column 5, lines 42 and 43).

In order to administer lavage solution to the patient, an administration port assembly 17 is employed through which lavage solution may be directed through passageway 19 and into the patient's airway (See Figure 6 of Russo; and column 5, lines 26-31). The seal 22 prevents any lavage solution administered through the administration port assembly 17 from entering the passage 34 (see Russo at column 5,

lines 37-40).

As can be seen, Russo teaches a suction catheter where lavage solution is administered to the patient in complete isolation from the suction catheter 44. Additionally, the suction catheter 44 is cleaned by lavage solution while completely isolated from the patient. It is therefore the case that both Russo and Niermann disclose suction catheter apparatuses where lavage solution is administered to the patient in complete isolation from the suction catheter, and where lavage solution is administered to the suction catheter in complete isolation from the patient. There is no motivation for one skilled in the art to combine these references because administration of lavage to the patient in complete isolation from the suction catheter and administration to the suction catheter in complete isolation from the patient is provided for in each one of the references alone. Regardless, even if such a combination were made incorporating the structure disclosed in Figures 5 and 6 of Russo into the suction catheter apparatus of Niermann, it would result in a newly formed suction catheter apparatus that functions so as to completely isolate the patient when lavage solution is applied to the suction catheter. This is because both of the references explicitly teach the isolation of the patient from lavage solution when lavage solution is administered to the suction catheter.

Turning now to the present application claim 1 calls for a respiratory suction apparatus that has a collar and a catheter that define a substantially uniform cylindrical space around a distal portion of the catheter. Further, a lavage port is in fluid

communication with the patient's artificial airway through the cylindrical space. As previously discussed, this structure is not present in either Niermann, Russo, or the combination of Niermann and Russo. The two references explicitly teach isolation of the patient's artificial airway when lavage solution is placed into communication with the catheter. As such, even if one skill in the art were somehow motivated to combine both Russo and Niermann, the resulting apparatus would not be the respiratory suction apparatus disclosed in claim 1 of Applicants' application.

Also, it would not have been obvious to modify either Niermann or Russo such that lavage solution is in communication with the artificial airway of the patient through a cylindrical space defined in part by the catheter, because such a configuration is explicitly stated as being undesirable in the references.

As such, Applicants respectfully submit that claim 1 defines over the combination of Niermann and Russo and is in condition for allowance. Further, all claims that depend directly or indirectly from claim 1 (claims 2-9) are also in condition for allowance. Their rejections being made moot due to the allowance of independent claim 1.

Also in the Office Action of May 1, 2003, claim 10 was rejected over the combination of Niermann and Russo. Claim 10 calls for a respiratory suction apparatus that has a substantially uniform cylindrical space defined by a collar and a catheter where a lavage port is in fluid communication with the patient's artificial airway through the cylindrical space. As such, Applicants respectfully submit that claim 10 defines over

the combination of Niermann and Russo for essentially the same reasons as discussed above with respect to claim 1 and is in condition for allowance. Further, all claims that depend from claim 10 (claims 11 and 12) are also in condition for allowance. Their rejections being made moot due to the allowance of claim 10.

Applicants respectfully submit that all claims are allowable and the application is in condition for allowance. Favorable action thereon is respectfully requested.

The Examiner is encouraged to call the undersigned at his convenience to resolve any remaining issues.

Respectfully submitted,

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